



BILLING CODE 6560-50-P

**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 180**

**[EPA-HQ-OPP-2014-0889; FRL-9929-74]**

**Zeta-cypermethrin; Pesticide Tolerances**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation amends the tolerances for residues of zeta-cypermethrin in or on corn, field, forage; corn, field, stover; and corn, pop, stover. FMC Corporation requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

**DATES:** This regulation is effective [*insert date of publication in the Federal Register*].

Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the Federal Register*], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

**ADDRESSES:** The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2014-0889, is available at <http://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

**FOR FURTHER INFORMATION CONTACT:** Susan Lewis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460-0001; main telephone number: (703) 305-7090; email address: [RDfRNotices@epa.gov](mailto:RDfRNotices@epa.gov).

## **SUPPLEMENTARY INFORMATION:**

### **I. General Information**

#### *A. Does this Action Apply to Me?*

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).

- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

*B. How Can I Get Electronic Access to Other Related Information?*

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at [http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab\\_02.tpl](http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl).

*C. How Can I File an Objection or Hearing Request?*

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2014-0889 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before *[insert date 60 days after date of publication in the **Federal Register**]*. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2014-0889, by one of the following methods:

- *Federal eRulemaking Portal*: <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

- *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

## **II. Summary of Petitioned-For Tolerance**

In the **Federal Register** of January 28, 2015 (80 FR 4525) (FRL-9921-55), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 4F8290) by FMC Corporation, 1735 Market St., Philadelphia, PA 19103. The petition requested to amend the tolerances in 40 CFR 180.418 for residues of the insecticide zeta-cypermethrin, S-cyano (3-phenoxyphenyl) methyl ( $\pm$ )(cis-trans 3-(2-2-dichloroethenyl)-2,2 dimethylcyclopropanecarboxylate, in or on corn, field, forage from 0.2 parts per million (ppm) to 9.0 ppm; corn, field, stover from 3.0 ppm to 30.0 ppm; and corn, pop, stover from 3.0 ppm to 30.0 ppm. That document referenced a summary of the petition prepared by FMC Corporation, the registrant, which is available in the docket, <http://www.regulations.gov>. Comments were received on the notice of filing. EPA's response to these comments is discussed in Unit IV.C.

Instead of the proposed tolerances in field corn stover (30.0 ppm) and popcorn stover (30.0 ppm), the Agency is establishing the tolerances at 30 ppm. The Agency establishes

tolerances using whole numbers for tolerances of 10 ppm or more, per the OECD's *User Guide ENV/JM/MONO (2011)2* for the OECD tolerance calculation procedure.

### **III. Aggregate Risk Assessment and Determination of Safety**

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe." Section 408(b)(2)(A)(ii) of FFDCA defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue...."

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for zeta-cypermethrin including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with zeta-cypermethrin follows.

Zeta-cypermethrin is an enriched isomer of the pyrethroid insecticide cypermethrin. In addition, alpha-cypermethrin is also an enriched isomer of cypermethrin. Although cypermethrin, zeta-cypermethrin, and alpha-cypermethrin are separate active ingredients with different end-use products, they are included together in the hazard evaluation for the purpose

of human health risk assessment. The toxicology database for the cypermethrins includes studies with cypermethrin and both of its enriched isomers, and is considered complete for the purpose of risk assessment.

The aggregate risk assessment for zeta-cypermethrin must consider potential exposure from all cypermethrins (i.e., cypermethrin, zeta-cypermethrin, and alpha-cypermethrin), since the three active ingredients are considered to be essentially the same from the mammalian toxicity perspective. The revised tolerances are associated with decreased pre-harvest intervals (PHIs) for field corn and popcorn—from 30 days for grain and stover and 60 days for forage to 7 days for all these commodities—and have no impact on the existing dietary exposure assessment for the cypermethrins. Corn forage and stover are livestock feed items and are not directly entered into the dietary exposure assessment, and EPA has determined that the existing tolerances for livestock commodities are adequate to support the changed use pattern. The existing zeta-cypermethrin use on corn was included in previous dietary exposure assessments. Decreasing the PHI and increasing the zeta-cypermethrin tolerances for field corn forage, field corn stover, and popcorn stover will have no impact on the dietary risk estimates, as they are already covered in the existing dietary assessment.

In the final rule published in the **Federal Register** of December 7, 2012 (77 FR 72975) (FRL-9371-7), EPA established tolerances for residues of zeta-cypermethrin in multiple commodities. Since the publication of that final rule, the toxicity profile of zeta-cypermethrin has not changed, and since the revised tolerances associated with decreased PHIs for field corn and popcorn have no impact on the existing dietary and aggregate risk determinations, the risk assessments that supported the establishment of the zeta-cypermethrin tolerances published in the December 7, 2012 **Federal Register** final rule remain valid. Therefore, EPA is relying on those

risk assessments in order to support the revised tolerances for zeta-cypermethrin in field corn forage, field corn stover, and popcorn stover.

An updated aggregate risk assessment was not needed to support the proposed increased tolerances for residues in field corn forage, field corn stover, and popcorn stover, and the increased tolerances will not result in a change in the previously estimated dietary (food and water) or residential exposure estimates for zeta-cypermethrin. For a detailed discussion of the aggregate risk assessments and determination of safety, refer to the December 7, 2012 **Federal Register** final rule and its supporting documents, available at <http://www.regulations.gov> in docket ID number EPA-HQ-OPP-2010-0472. EPA is relying on those supporting risk assessments and findings to support this final rule.

Based on the risk assessments and information described in this unit, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children, from aggregate exposure to zeta-cypermethrin residues. Additional information can be found in the document: “Zeta-Cypermethrin – Human Health Risk Assessment for a Petition to Amend (Increase) the Established Tolerances for the Insecticide in Field Corn and Popcorn Stover, and in Field Corn Forage,” available in docket ID number EPA-HQ-OPP-2014-0889.

#### **IV. Other Considerations**

##### *A. Analytical Enforcement Methodology*

Adequate tolerance enforcement methods are available in Pesticide Analytical Manual (PAM) Volume II for determining residues of alpha-cypermethrin, cypermethrin, and zeta-cypermethrin in plant (Method I) and livestock (Method II) commodities. Both methods are gas chromatographic methods with electron-capture detection (GC/ECD), and have undergone

successful Agency petition method validations (PMVs). These methods are not stereospecific; thus no distinction is made between residues of cypermethrin (all 8 stereoisomers), alpha-cypermethrin (enriched in 2 isomers), and zeta-cypermethrin (enriched in 4 isomers). The January 1994 Food and Drug Administration (FDA) PESTDATA database (PAM Volume I) indicates that residues of cypermethrin are completely recovered (>80%) using multi-residue method sections 302 (Luke), 303 (Mills, Onley, and Gaither), and 304 (Mills fatty food).

#### *B. International Residue Limits*

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

There are no Codex MRLs for cypermethrin, which includes both alpha- and zeta-cypermethrin, established in corn forage or stover.

#### *C. Response to Comments*



One comment was received from the general public, urging the Agency to deny the request. The commenter particularly addressed toxicity to bees and other insects, and human toxicological and reproductive effects.

The Agency understands the commenter's concerns, and recognizes that some individuals believe that certain pesticide chemicals should not be permitted in food. Regarding effects to bees and other insects, the safety standard for approving tolerances under section 408 of FFDCA focuses on potential harms to human health and does not permit consideration of effects on other species or the environment. The existing legal framework provided by section 408 of FFDCA states that tolerances may be set when persons seeking such tolerances or exemptions have demonstrated that the pesticide meets the safety standard imposed by that statute. When new or amended tolerances are requested for residues of a pesticide in food or feed, the Agency, as is required by Section 408 of FFDCA, estimates the risk of the potential exposure to these residues by performing an aggregate risk assessment. Such a risk assessment integrates the individual assessments that are conducted for food, drinking water, and residential exposures. Additionally, the Agency, as is further required by Section 408 of the FFDCA, considers available information concerning what are termed the cumulative toxicological effects of the residues of that pesticide and of other substances having a common mechanism of toxicity. Therefore, these assessments consider both exposure and toxicological effects—including information concerning the reproductive effects of the pesticide—in reaching a conclusion as to whether or not the reasonable certainty of no harm decision can be made. The Agency has concluded after this assessment that there is a reasonable certainty that no harm will result from exposure to the residues of zeta-cypermethrin. Therefore, the proposed tolerances are found to be acceptable.

## V. Conclusion

Therefore, tolerances are established for residues of zeta-cypermethrin, *S*-cyano (3-phenoxyphenyl) methyl ( $\pm$ )(*cis-trans* 3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropanecarboxylate, in or on corn, field, forage at 9.0 ppm; corn, field, stover at 30 ppm; and corn, pop, stover at 30 ppm.

## VI. Statutory and Executive Order Reviews

This action establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

## **VII. Congressional Review Act**

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

**List of Subjects in 40 CFR Part 180**

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: July 22, 2015.

Susan Lewis,

*Director, Registration Division, Office of Pesticide Programs.*

Therefore, 40 CFR chapter I is amended as follows:

**PART 180--[AMENDED]**

1. The authority citation for part 180 continues to read as follows:

**Authority:** 21 U.S.C. 321(q), 346a and 371.

2. In § 180.418, revise the entries for “corn, field, forage,” “corn, field, stover,” and “corn, pop, stover” in the table in paragraph (a)(2) to read as follows:

**§ 180.418 Cypermethrin and isomers alpha-cypermethrin and zeta-cypermethrin; tolerances for residues.**

(a) \* \* \*

(2) \* \* \*

Commodity	Parts per million
****	***
Corn, field, forage	9.0
****	***
Corn, field, stover	30
****	***
Corn, pop, stover	30
****	***

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